

REMARKS

This is in response to the Office Action mailed October 26, 2009 ("the Office Action"). By this Amendment, claims 1, 3, 5-20, 22-52, 59 and 60 have been amended, new claim 61 has been added, and claim 21 has been canceled without prejudice or disclaimer. The new claim and claim amendments are fully supported by the application as-filed, and no new matter has been added. Claims 1, 3, 5-20 and 22-61 remain pending in this application.

I. Election/Restriction

In the Office Action, the Examiner finds the Applicant's traversal on the grounds that the claims allegedly drawn to Groups I-IV (See Restriction Requirement dated June 19, 2009) do not impose a serious burden as unpersuasive. See Office Action, p. 2. However, the Restriction Requirement incorrectly states that the only linking element between the groups is a vacuum source, and that the use of a vacuum source is well known in the art. See Restriction Requirement, p. 2. Instead, Applicant submits that with at least respect to alleged Groups I-III, an additional special technical feature linking the alleged groups includes a vacuum source used for facilitating insertion of bone substitute in the bone. As described below, such a technical feature is not known in the prior art.

For at least the foregoing reason, Applicant respectfully request withdrawal of the Finality of the Restriction Requirement at least with respect to alleged Groups I-III.

II. **Information Disclosure Statement**

In the Office Action, the Examiner states that the "information disclosure statement filed July 20, 2009 fails to comply with 37 C.F.R. 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered." Office Action, p. 3. However, the Examiner indicated on the PTO/SB/08 that "[a]ll references [were] considered except where lined through." As such, the Applicant kindly requests clarification as to whether the entire IDS was not considered as suggested by the Office Action, or, whether the IDS was considered except where lined though on the PTO/SB/08 submitted July 20, 2009.

Further, with respect to those references which have been lined through as not considered, specifically, all lined though references on page 6 of the PTO/SB/08, the Machine Translation of JP 1139516 listed on page 7 of the PTO/SB/08, and the English-language translation of ES 2 178 556 A1 listed on page 8 of the PTO/SB/08, Applicant states that each reference, was properly submitted in accordance with 37 C.F.R. § 1.98(a)(2). Evidence of proper submission can be found by looking at the Image File Wrapper (IFW) such as in PAIR.

With respect to the lined through referenced Co-pending Application Nos., Applicant hereby submits the U.S. Patent Application Publication of each listed Co-pending Application. Further, Applicant hereby lists the reference Co-pending Applications on a concurrently filed IDS.

Also, the Examiner requests the Applicant to "fill in the 6th Column of the IDS (relevant passages/figures). . . [and] to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention ..." Office Action, p. 2. Applicant kindly directs the Examiner's attention to 37 C.F.R. § 1.98(a) which lists the minimum requirements for compliant information disclosure statements. In particular, Applicant notes that there is no requirement to fill in the 6th column to include relevant passages and figures. Rather, there is merely a requirement under § 1.98(a)(3)(i) necessitating "[a] concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. The concise explanation may be either separate from applicant's specification or incorporated therein." 37 C.F.R. § 1.98(a)(3)(i) (emphasis added); See also M.P.E.P. § 609.04(a). Applicant has satisfied this requirement by the submission of "Information Disclosure Statement Under 37 C.F.R. §1.97(b)" transmittal letter filed concurrently with the PTO/SB/08. Further, Applicant kindly directs the Examiner's attention to M.P.E.P. §609.04(a) which states that "a concise explanation [including those which point out the relevant pages and lines] is not required for English language information." See M.P.E.P § 609.04(a)(emphasis added). Therefore, Applicant respectfully asserts that the IDS filed July 20, 2009 complies with all requirements for information disclosure statements and the "Examiner[] must consider all citations." See M.P.E.P § 609.05(b)

With regard to the IDS filed October 5, 2006, we have noticed a small typographical error in the non-patent literature section. In particular, we note that the

article listed as "Lidgren., 'Bone Substitutes', Karger Gazette No. 65 2003; Bone and Joints" should have been listed as -- Bone Substitutes', Karger Gazette No. 65 2002; Bone and Joints --. (Emphasis added.) In light of this error, please see the concurrently filed IDS and SB/08 resubmitting the article with the correct date. Applicant respectfully requests the Examiner indicate the reference as considered in the next Office Action.

III. 35 U.S.C. § 101 Rejection

Applicant respectfully traverses the Examiner's rejection of claims 9, 10 and 34-36 under 35 U.S.C. § 101. Applicant does not necessarily agree with the characterization that Applicant's claims "include a human within their scope and are non-statutory." Office Action, p. 3.

Applicant respectfully submits that claims 9, 10, and 34-36 are each directed to a "device for providing spongy bone with bone substitute and/or bone reinforcing material," and not to the human body as alleged by the Examiner (claim 1, emphasis added). According to Section 2105 of the M.P.E.P., "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."

Each of claims 9, 10, and 34-36, as a whole, do not encompass a human body. Instead, each of claims 9, 10, and 34-36 is directed to a system for providing spongy bone with bone substitute and/or bone reinforcing material, including, among other things, at least one perforating device for making at least one hole in a spongy bone, at least one flushing device or rinsing device for flushing or rinsing the hole with a rinsing

agent, at least one supply device for permitting supply of bone substitute and/or bone reinforcing material to the hole in the spongy bone, and at least one vacuum source for generating a vacuum. The recitations of "the hole," "the spongy bone," and the like are directed to intended use and are functional in nature, and are therefore not positively claimed. Thus, claims 9, 10, and 34-36 do not positively set forth the human body as part of the claimed subject matter. Accordingly, Applicant respectfully submits that each of claims 9, 10, and 34-36 is directed to patentable subject matter.

As further evidence, Applicant directs the Examiner's attention to the volume of issued patents reciting human body parts within their claims in a functional manner. These claims were correctly deemed appropriate by the issuing Examiner. See, for example, U.S. Patent 5,295,483 reciting "said patient examining table being adapted to support a human patient having therein a target an ultrasound probe..." and U.S. Patent 5,344,383 reciting "[a] method . . . which comprises the following steps: (a) connecting one branch of the three-forked connector with the hose portion inserted into the human body . . ." As such, there is a long-standing belief by the U.S.P.T.O. that claims reciting human body parts in a functional manner are indeed directed to statutory subject matter.

IV. 35 U.S.C. § 112, Second Paragraph, Rejection

In the Office Action, claims 1, 3, 5-52, 59, and 60 were rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. In particular, the Office Action alleges that there is "an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear." Office Action, p. 4.

Generally, the scope of a claim will be considered definite where each recited limitation is definite. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971). Accordingly, applicant may use functional language, alternative expressions, negative limitations or any style of expression which makes clear the metes and bounds of the subject matter for which patent protection is sought.

The Examiner suggests that "[s]ince claiming the combination of the apparatus and the hole makes such claims(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the hole. As such, the claim(s) would be directed to the subcombination, the device, and will be considered for examination purposes, wherein the hole is merely functionally recited." Office Action, p. 4.

As discussed above, the claimed features include, *inter alia*, at least one at least one perforating device configured to make at least one hole in the spongy bone, at least one flushing or rinsing device configured to flush or rinse the hole with a rinsing agent, at least one supply device configured to supply the bone substitute and/or bone reinforcing material to the hole in the spongy bone, and at least one vacuum source configured to generate a vacuum in the hole in the spongy bone. Further, the recitations of "the hole," "the spongy bone," and the like are merely functional in nature, and are therefore not positively claimed.

Applicant submits that the Examiner's assertion of inconsistency between the preamble and the body of the claim contradicts with well defined principles of patent

law. In particular, Applicant notes "a claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). Further, "[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). As such, the claims must be read as a whole. Applicant therefore request reconsideration and withdrawal of the Examiner's rejection of claims 1, 3, 5-52, and 59-60.

Further, the Examiner indicates there is insufficient antecedent basis for the recitation "said material" in claim 1. Applicant submits that the above recited feature has been canceled from claim 1 thereby rendering the rejection moot.

In regard to claim 17, the Office Action indicates that the recitation "a first and second cannula or needle are insertable . . . such that they are simultaneously directed into the hole" is unclear since "the applicant is only claiming that only either the cannulas or the needle are insertable but then claims that both can be driven into the hole." Office Action, p. 5. By this Amendment, Applicant hereby amends claim 17 to recite "wherein at least a first cannula or needle and a second cannula or needle (19, 20) are configured to be insertable . . . such that they are simultaneously directed into the hole." Accordingly, Applicant submits that this feature is sufficiently clear and the rejection has been rendered moot.

In regard to claims 41-43, the Office Action alleges that there is "insufficient antecedent basis for" the recitation "wherein a device" because it "is unclear if the applicant meant to disclose the same device as in claim 1 or further comprising another device." Office Action, p. 5. Accordingly, Applicant has amended each of claims 41-43 to each recite a "secondary device" thus rendering the rejection moot.

In regard to claim 46, the Office Action alleges that "the phrase 'such as' renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention." Office Action, p. 5. Accordingly, Applicant has canceled the phrase "such as water" from claim 46 thereby rendering the rejection moot.

V. Claim Rejections under 35 U.S.C. § 102(b)

a. Reiley et al.

In the Office Action, claims 1, 3, 11-13, 17, 18, 20-21, 23, 26-29, 32-37, 41-45, 51, 52, and 60 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,248,110 to Reiley et al. ("Reiley"). Applicant respectfully traverses these rejections.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Reiley does not disclose all of the elements of independent claim 1 as amended.

Independent claim 1, as amended, recites, among other things, "said vacuum source (9) is further configured to suck the bone substitute and/or bone reinforcing

material (3) into the hole (5) in the spongy bone (1)." Applicant submits that the language "configured to," as used throughout the claims, means that the system must, at the very least, be "capable of" performing the recited function. It is Applicant's position that such language imparts structural limitations on the claim and must be given weight during examination. In particular, the ordinary meaning of the word "configure" is "to set up for operation esp. in a particular way." (Merriam Webster's Collegiate Dictionary, page 261, 11th ed. 2007.) Thus, a device, in order to be configured to perform a desired function, must not only be capable of performing the desired function, but also be set up to perform the desired function. Therefore, any required connections and programming must be in place for a device to be "configured to" perform a specific task. In a case where any connections and/or programming are not disclosed by a reference, motivation would be required to explain why one of ordinary skill in the art would modify such a device to set it up to perform the desired function. Here, there is no evidence or suggestion that the vacuum source element 86 or element 94 of Reiley is capable of generating a vacuum which is configured to suck bone substitute or bone reinforcing material into the hole.

Element 86 of Reiley is connected to tool 48 including tube 50 having an expandable body 56 at the distal end thereof. See, Reiley Fig. 4. As disclosed in Fig. 5L, tube 50 and expandable body 56 are first removed from the body thereby disconnecting the vacuum source 86 from the body. Subsequently, as shown in Fig. 5M, an injector tube 96 may be inserted into the body to inject filling material 96. As such, the vacuum source 86 is not in communication with the filling material 96, and therefore, cannot suck bone substitute and or bone reinforcing material into the hole in

the spongy bone as required by independent claim 1. Further, Applicant notes that Reiley teaches away from using element 86 to suck bone substitute and or bone reinforcing material into the hole in the spongy bone. In particular, Reiley teaches using the expandable body 56 of the tube 50 (connected to the vacuum source 86) to spread the material more uniformly within the cavity, while the material is being pushed in. See, Reiley col. 10., ll. 23-25. By using the expandable body 56 during injection of the bone substitute, the pressure inside the bone will increase. An increase in pressure is directly opposite from the effect achieved by using a vacuum source.

Element 94 of Reiley is not a vacuum source, but rather an injector gun. As such, Reiley's injector gun 94 is not capable of generating a vacuum in the hole of the spongy bone as required by independent claim 1. Rather, the injector gun 94 is only provided to push material into the hole and not to provide vacuum to the hole. Even assuming such a broad interpretation of the injector gun 94 would be appropriate, which Applicant does not concede, the injector gun 94 of Reiley still is not capable of sucking the bone substitute or bone reinforcing material into the hole in the spongy bone. Rather, by way of manually operated injection grip 98, injector gun 94 may push material into the bone.

For at least the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102(b) rejection of independent claim 1 based on Reiley. Further, Applicant submits that claims 3, 11-13, 17, 18, 20-21, 23, 26-29, 32-37, 41-45, 51, 52, and 60 depend from independent claim 1, and, are therefore allowable for at least the same reasons as independent claim 1, as well as for their additionally recited features.

b. Andrew et al.

In the Office Action, claims 1, 21, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,074,358 to Andrew et al. ("Andrew").

Applicant respectfully traverses these rejections.

Independent claim 1, as amended, recites, among other things:

at least one perforating device (4) configured to make at least one hole (5) in the spongy bone (1), at least one flushing or rinsing device (6) configured to flush or rinse the hole (5) with a rinsing agent (7), at least one supply device (8) configured to supply the bone substitute and/or bone reinforcing material (3) to the hole (5) in the spongy bone (1), and at least one vacuum source (9) configured to generate a vacuum in the hole (5) in the spongy bone (1), suck the rinsing agent (7) into the hole (5) in the spongy bone (1), and to suck rinsing agent (7) and tissue material out of said hole (5).

In contrast, Andrew discloses a device/technique for liquefying, or gelifying, a hardened cataractic lens nucleolus. Andrew, Abstract. The technique involves making a small incision in a cornea of a human eye, irrigating the lens with hot and cool balanced salt solutions (BSS), and aspirating the fluids and lens out of the incision of the eye.

Andrew, col. 4, ll. 25-55.

Applicant respectfully asserts that the device/technique of Andrew fails to disclose a perforating device configured to make a hole in a bone. Rather, the alleged perforating device of Andrew, is only disclosed as making a hole in an eye. Eye tissue is much softer than bone material. As such, a device capable of making an incision in the very soft tissue of the eye is not necessarily capable of making hole in the hard material of a bone. Further, Andrews fails to disclose a supply device configured to supply bone substitute and/or bone reinforcing material. Rather, Andrew only discloses the use of two salt solutions and is silent regarding any ability to supply bone substitute

and/or bone reinforcing material. Bone substitute and/or bone reinforcing material has very different properties than that of salt solution, a device capable of supplying salt solutions, may not necessarily be capable of supplying bone substitute and/or bone reinforcing material.

Further, the device of Andrew is not capable of sucking anything into any hole. This is true because the outlet of the vacuum source of Andrew is positioned next to the outlet of the supply devices. See, Andrew Fig. 1 and 2. As such, if the vacuum source is activated at the same time as any of the supply devices, any material from the supplying tubes will be sucked directly into the vacuum tube. For this reason, the device of Andrew would be unable to suck anything into a hole. Further, the vacuum source of Andrew is only disclosed as sucking a liquefied cataractous lens nucleolus from the eye. Applicant respectfully submits that a liquefied cataractous lens nucleolus is thinner than bone reinforcing material and therefore, requires less pressure in order to remove via suction. Therefore, Andrew does not disclose a vacuum source capable of sucking bone substitute and/or bone reinforcing material, as required by independent claim 1.

For at least the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the Section 102(b) rejection of independent claim 1 based on Andrew. Further, Applicant submits that claims 21 and 22 depend from independent claim 1, and, are therefore allowable for at least the same reasons as independent claim 1, as well as for their additionally recited features.

VI. Claim Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 38-40, 46-50, and 59 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley in view of *In Re Leshin*; claim 5 was rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley in view of U.S. Patent No. 5,269,785 to Bonnutti ("Bonnutti"); claim 9 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of U.S. Patent No. 3,965,910 to Fischer ("Fischer"); claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley in view of U.S. Patent No. 5,997,533 to Nies et al. ("Nies"); claims 5 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley in view U.S. Patent No. 3,837,379 to McDonald ("McDonald"); claim 10 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of McDonald and further in view of Fischer; claim 8 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of Fischer; claims 14, 15 and 30 were rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of *In re Aller*; claim 16 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of U.S. Patent Application Publication No. 2002/0156483 to Voellmicke ("Voellmicke"); claim 19 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of Fischer; claims 24 and 25 were rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of Bonutti; and claim 31 was rejected under 35 U.S.C. §103(a) as unpatentable over Reiley in view of U.S. Patent Application Publication No. 2004/0006347 to Sproul ("Sproul"). Applicant respectfully traverses these rejections.

A proper *prima facie* case of obviousness requires, *inter alia*, that the prior art references when combined must teach or suggest all the claim limitations. See

M.P.E.P. § 2142. Applicant respectfully asserts that each of the applied secondary references fail to cure the deficiencies of Reiley with respect to independent claim 1. As such, each of claims 5-10, 14-16, 19, 24, 25, 31, 38-40, 46-50, and 59 are allowable for at least the same reasons as independent claim 1. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) of claims 5-10, 14-16, 19, 24, 25, 31, 38-40, 46-50, and 59.

VII. New Claim

Applicant has added new claim 61. The claimed features are disclosed in this application, and do not constitute new matter. The cited references do not anticipate or suggest the subject matter recited in claims 61.

In particular, new claim 61 recites, among other things, "at least one vacuum source (9) configured to generate a vacuum in the hole (5) in the spongy bone (1), and suck the bone substitute and/or bone reinforcing material (3) into the hole (5) in the spongy bone (1); wherein the vacuum source (9) is configured to generate a vacuum of between about 0.5 bar and about 0.92 bar of the hole (5) in the spongy bone (1)." The Office Action alleges that [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have the vacuum generate a vacuum between .5 bar and .92 bar . . . since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art." Office Action, p. 18. However, as detailed above in connection with the 102 rejection of claim 1 by Reiley, the general conditions of the claim have not

been met. Rather, the vacuum source of Reiley has not been shown as configured to generate a vacuum in holes in a bone or suck bone filling material into a hole a bone.

VIII. Conclusion

Applicant submits that the claimed invention is neither anticipated nor rendered obvious by the prior art references cited against the claims. Applicant therefore requests reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the alleged related art, with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: Jessica F. Winchester
Jessica F. Winchester
Reg. No. 65,285
(202) 408-4000